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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/678,212 | 10/02/2003 | Michael Hawley | 6794S-000028/US/01 | 2159 |

28997 7590 10/11/2005

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| EXAMINER | |
|---|---|
| DESAI, RITA J | |
| ART UNIT | PAPER NUMBER |
| 1625 | |

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/678,212 | HAWLEY ET AL. | |
| | Examiner | Art Unit | |
| | Rita J. Desai | 1625 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *13-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/2005*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *9/28/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-40 are pending.

The claims are drawn to pharmaceutical compositions , method of using the compositions and method of making the crystalline salt.

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to pharmaceutical compositions , classified in class 546, 514 and various, subclasses.

II. Claims 13-24, 29-40 drawn to method of treating sexual dysfunction and increasing sexual desire, classified in class 514 and various subclasses.

III. Claims 13-24 , drawn to a process of making a crystalline salt, classified in class 546, 514, and various subclasses.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of using to treat sexual dysfunction can be done by other drugs available on the market.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Mr. Jamie Davis on 9/28/05 a provisional election was made with traverse to prosecute the invention of group I , claim 1-12 . Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If applicant 's traverse on the grounds that the inventions are not patentably distinct, applicants should submit evidence or identify such evidence now of record showing the groups

to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art , the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

If applicants elect group I drawn to the compositions , and if it is found to be allowable then the method of treating group II , limited to the scope of the allowable compositions will be rejoined.

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim recites so many provisoes it is unclear what applicants invention really is.

The claim is defined by negative limitations and does not clearly define what applicants invention actually is.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for R-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-I,j]-qunoline-2(1H)-thione does not reasonably provide enablement for the full scope of formula I coupled with the fact that the formula I is not clearly defined . The specification does not enable any person

skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

**1) The breadth of the claims:** The instant claims encompass many compounds from a tricyclic with a 5 membered carbocylic ring to a tricyclic with 2 6 membered ring with a 2 –3 hetero rings or just one hetero ring having many large electron withdrawing and bulky groups substituted on it to a moiety having heterocyclic rings. These compounds cover a very wide range of compounds.

**2) The nature of the invention:** The invention is a drawn to making a pharmaceutical composition with a sweetener , used for treating sexual dysfunction.

**3) The state of the prior art:** The prior art teaches numerous pharmaceutical ..

**4) The level of one of ordinary skill:** The ordinary artisan is highly skilled.

**5) The level of predictability in the art:** It is noted that the pharmaceutical art is unpredictable , requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F. 2d 833, 166 USPQ 18(CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. The level of unpredictability is in the art is very high. The compounds which differ by a methyl group also show different properties, for e.g. theophylline and caffeine. One of them is a bronchodialator and they differ only by a methyl group. Thus the whole genus without any clear definition since the claim has so many negative limitations makes the predictability even less.

**6) The amount of direction provided by the inventor:** The inventor provides very little direction in the instant specification. There is only one example of the pharmaceutical compositions.

**7) The existence of working examples:** The instant specification does not have any working examples.

**8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure:** Since there are no working examples, the amount of experimentation is very high and burdensome.

Taking the above eight factors into consideration, it is not seen where the instant specification enables the ordinary artisan to make and/or use the instantly claimed invention.

Genetech Inc Vs Nova Nordisk 42 USPQ 2d 1001.

"A patent is not a hunting license. It is not a reward for search but compensation for its successful conclusion and patent protection is granted in return for an enabling disclosure of an invention , not for vague intimations of general ideas that may or may not be workable."

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5273975 Moon et al

WO02/062315 Martino A et al

WO 00/40226 Meglasson et al

Chang et al Fast Dissolving Tablets

US 6149,941 Schwarz et al

US 4740376 Yang R,

US 5126151 Bodor et al ,

GB 2187074 Cascales Maria.

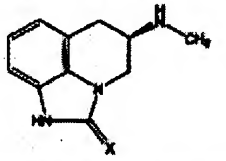
Applicants claims are drawn to a pharmaceutical composition of known compounds but with a sweetener.

**Determination of the scope and content of the prior art (MPEP §2141.01)**

The 5273975 Moon et al teaches s a similar core of compounds .

WO02/062315 Martino A et al ( 102a date or 102 e date) teaches the compositions of a sexual dysfunction pharmaceutical with a pharmaceutical acceptable excipient , adapted for delivery by a route of administration that entails the organs of taste . See abstract. The reference teaches the prefeered compound s being

Preferred compounds useful in compositions of the invention are those disclosed generically or specifically in above-cited U.S. Patent No. 5,273,975. Especially preferred compounds are those of formula (II)



(II)

wherein X is O or S, and pharmaceutically acceptable salts thereof.

and applicants preferred compound is a close similarity , but the genus reads on the compounds .

WO 00/40226 Meglasson et al also teaches similar compounds for treating sexual dysfunction.

Chang et al Fast Dissolving Tablets see sugar based excipients page 56, teaches Ascertainment of the difference between the prior art and the claims (MPEP §2141.02) t saccarides.

US 6149,941 Schwarz et al prior art reference teach similar compounds for the same use and also use of sweeteners to make fast soluble drugs , for easy delivery and also for solubility.

The 6149941 teaches a large list of sweeteners for pharmaceutical compositons. See the whole document , column 1, 2, 3. Column 3 clearly teaches using it with the various active ingredients.

US 4740376 Yang R, teaches protecting a flavoring ( bio- effective) ingredient and also providing a controlled release thereof. See column 1 lines 10-24., column 4 lines 35-51. Line 51 column 4 describes cyclamate as a artificial sweetener.

US 5126151 Bodor et al , also teaches uses artificial sweeteners such as cyclamate see claim 8.

GB 2187074 Cascales Maria. Whole document teaches use of cyclamate as a sweetener for food products, along with saccharine , glucose, sorbitol etc.

All teach the use of cyclamate as a sweetener. (cyclohexyl sulfamic acid )

**Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)**

The references specifically do not mention making the pharmaceutical composition with a sweetener and compound R-5,6-dihydro-5-(methylamino)-4H-imidazo[4,5-I,j]-qunoline-2(1H)-thione.

**Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)**

The prior art clearly points to effective use of sweeteners with the different active ingredient ofr either taste or solubility. One of skill in the art would have found it obvious to make pharmaceutical compositions with artificial sweeteners.

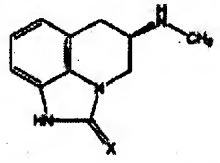
Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/062315 Martino A. et al. and GB 2187074 Cascales Maria

Applicants claims are drawn to pharmaceutical compositions of compounds of formula I with artificial sweeteners.

**Determination of the scope and content of the prior art (MPEP §2141.01)**

The WO 02/062315 document clearly teaches ( 102a date or 102 e date) teaches the compositions of a sexual dysfunction pharmaceutical with a pharmaceutical acceptable excipient , adapted for delivery by a route of administration that entails the organs of taste . See abstract. The reference teaches the prefeered compound s being

Preferred compounds useful in compositions of the invention are those disclosed generically or specifically in above-cited U.S. Patent No. 5,273,975. Especially preferred compounds are those of formula (II)



(II)

wherein X is O or S, and pharmaceutically acceptable salts thereof.

and applicants preferred compound is a close similarity, but the genus reads on the compounds.

GB 2187074 Cascales Maria. Whole document teaches use of cyclamate as a sweetener for food products, along with saccharine , glucose, sorbitol etc.

**Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)**

WO 02062315 teaches the pharmaceutical compositions which would be administered via the organ of taste .

GB 2187074 teaches the use of sweeteners such as saccharin, cyclamates and such which are obviously administered by the organ of taste.

Thus one of skill in the art would have been motivated and found it obvious to use the sweeteners from GB '074 in making the pharmaceutical compositions of WO '315.

***Conclusion***

Thus the claims 1-12 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday,9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai

Primary Examiner
Art Unit 1625

R.D.
September 28, 2005